DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 5, 2015

Tyece Ltd
% Guenter Ginsberg
Consultant
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, Florida 34135

Re: K150386
Trade/Device Name: Tyece OTC TENS Device, Model SEM44
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: April 4, 2015
Received: September 30, 2015

Dear Mr. Ginsberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150386

Device Name
Tyece OTC TENS Device, Model SEM44

Indications for Use *(Describe)*
The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the lower back, arms, or legs due to strain from exercise or normal household activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY (revised 6.30.2015)

Date of Summary Prepared: 02/05/2015

1. Submitter's Name: Tyece Ltd.

Address: Unit 801, Block A, Po Lung Centre, 11 Wang Chiu Rd., Kowloon Bay, Kowloon, Hong Kong, SAR

Contact person: Parshid Falahati

Tel: 852- 2 - 3497456

Fax: 852 -2 - 3499166

E-mail sales@tyece.com

2. Proposed New Device:

Trade Name: Tyece OTC TENS Device, Model SEM44

Classification Name: TENS

Regulation Number: 882.5890

Product Code: NUH

Device Class: II

3. Predicate (cleared) Device:

Counter TENS Device, Model PTS-IV

510(k) Number: K132993

Manufacturer: Counter Scientific Development Ltd.

4. Description of Proposed Device:

The Tyece OTC TENS Device, Model SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 0 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under K132588.
The device has been tested to and meets the requirements of the following recognized consensus standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

5. Indication for Use:

This Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the lower back, arms, or legs due to strain from exercise or normal household work activities.

6. Environment of Use:

Clinics, Hospitals and home environments

7. Contraindications:

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

8. Technological Characteristics Compared to the Predicate Device

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle pain relief, Model PTS-IV, The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle areas. Outputs are almost the identical, each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500 Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both devices are transiting pulses by the use of Electrode Pads. Both are portable devices. Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicate device. The differences that exist between the devices are insignificant in terms of safety or effectiveness.

Differences:
1. Device SEM44 has 15 preset programs, while the predicate device has 7.
2. Intensity levels of SEM44 are selectable from 0 to 50, while the predicate device is from 0 to 16, however, the maximum intensity settings of both units produce very similar outputs to the electrode pads. The SEM44 model can be adjusted in finer increments.
3. All other parameters such as waveform, frequency, pulse width, output current and voltage, although not exactly similar to this particular predicate, they do not raise any new questions of safety or effectiveness.
Note: It is very difficult, if not impossible, to find predicate devices that completely match the specifications of the subject device.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Savia did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the SEM44 vs. the predicate. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

a. **EMC and electrical safety**

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

b. **Biocompatibility**

The electrode pads are the only body contacting parts. They have been FDA cleared for OTC under K132588. The patient contacting electrodes comply with ISO 10993 and are considered Class A $\leq$ 24 hrs contact.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. The software of this device carries a MODERATE level of concern. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Tyece OTC TENS Device, Model SEM44 can be cleaned by the use of the methods described in the Instruction Manual.

10. Conclusions:

The Tyece OTC TENS Device, Model SEM44 has the same intended use and similar technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the predicate device.

Output Specifications:

Parameter		Your device	Predicate Device
Mode or Program Name		PAIN THERAPY DEVICE, SEM44	PAIN THERAPY DEVICE, PTS-IV
Waveform (e.g. positive-going, reverse, biphasic)		Biphasic	Positive-going, Reverse and Biphasic
Shape(e.g., spike, rectangular, square ware)		Square ware	Square ware
Maximum Output Voltage (Volts) (+/-15%)		70vp p@500 Ω	69.2vp p@500 Ω
		110vp p@2K Ω	86.4vp p@2K Ω
		190vp p@10K Ω	88.8vp p@10K Ω
Maximum Output Current (+/-15%)		86mA@500 Ω	69.2mA@500 Ω
		23.3mA@2K Ω	21.6mA@2K Ω
		3.75mA@10K Ω	4.4mA@10K Ω
Duration of primary Phase		0	0
Pulse Duration		50-360μS	200μS
Frequency		1-150Hz	1-136Hz
For multi Program waveforms only:	Symmetrical Programs	N/A	N/A
	Pulse duration		
Net Charge (micro coulombs μC) (per pulse) (if zero, State method of achieving zero net charge)		0.001μC@500 Ω	0.0013μC@500 Ω
Maximum Phase Charge (mC)		0.0454mC@500 Ω	0.0135mC@500 Ω
Maximum Current Density (mA/cm2, r.m.s)		0.790mA/cm2@500 Ω	3.270mA/cm2@500 Ω
Maximum Average Current (average absolute value), mA		16.0mA	2.218mA
Maximum Average Power Density, (W/cm2)(using smallest electrode conductive surface area)		0.00632W/cm2@500 Ω 1.0S	0.00116W/cm2@500 Ω 1.0S
Burst Mode(i.e. pulse trains)	(a) Pulses per burst	4	4/2
	(b) Bursts per second	4/83Hz	30/136Hz
	(c) Burst duration (seconds)	180μS	800μS/400μS
	(d) Duty Cycle	35ms/60ms	24ms/54.4ms
ON Time (seconds)		2s	0.5s
OFF Time (seconds)		2s	0.5s
Additional Features (specify, if applicable)		N/A	N/A
Electrode area:		20.25sqcm x 4 (81sqcm)	21.16sqcm x 4(84.64sqcm)

Basic Unit Characteristics:

Parameter		Your Device	Predicate Device
510(k) Number		K150386	K132993
Device Name and See attached photo Program		PAIN THERAPY DEVICE SEM44	PAIN THERAPY DEVICE PTS-IV
Manufacturer		SAVIA LTD.	COUNTER Scientific Development (GZ) Limited
Power Source		4.5V(batteries, 3x1.5V AAA)	3.7v Lithium (Power supply)
Method of Line Current Isolation		N/A	N/A
Patient Leakage Current		N/A	N/A
Normal Condition (μA)		N/A	N/A
Single Fault Condition (μA)		N/A	N/A
Average DC current through electrodes when device is on but no pulse are being applied (μA)		0μA	0μA
Numbers of Output Modes		15 Modes(01-15)	7 modes(A,B,C,D,E,F,ALL)
Number of Output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	PCB Insulation Boost Isolation	Boost Isolation
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage
Software/firmware/microprocessor control?		Yes	Yes
Automatic overload trip?		No	No
Automatic no-load trip?		Yes	Yes
Automatic shut off?		Yes	Yes
Users override control?		Yes	Yes
Indicator display	On/off status?	Yes	Yes
	Low battery?	Yes	Yes
	Voltage/current level? Only voltage level display	Yes for voltage	Yes for voltage
Timer range (minutes)		5-100min	20-40 min
Compliance with voluntary standards?		Yes	Yes
Compliance with 21CFR898-7?		Yes	Yes
Dimensions		L135xW65xT20mm	L120xW70xT18mm
Housing materials and construction		ABS	ABS